MANUFACTURING SYSTEMS ASSESSMENT PROCEDURE - CHECKLIST FOR SUPPLIER CERTIFICATION

DOCUMENT IDENTIFIER: A-SP-ELMF520-02-0 Rev B, 05-Oct-1989

ABSTRACT: This procedure is used in support of EL-MF520-00, *Supplier Certification Policy.* This document details the process and support requirements outlined in the Supplier Certification Policy.

APPLICABILITY: All manufacturing systems supporting the requirements for Digital Supplier Certification must adhere to this document.

STATUS: APPROVED 05-Oct-1989; use VTX SMC for current status.

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APPROVAL: The Supplier Certification Policy has been approved for implementation throughout Digital Equipment Corporation.

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1 INTRODUCTION

This procedure shall be used in support of EL-MF520-02, *Supplier Certification Policy.* The Certification Policy outlines requirements for certification; the Manufacturing Systems Assessment checklists provided in this document detail the requirements of the Certification Policy.

It is recommended that the user of this document have previous training and experience in the performance of manufacturing assessment.

1.1 PURPOSE

Each section of this document must be interpreted for the intent that it conveys. For example:

a. Many sections require a "plan". The intent of this requirement is that a proper, thoughtfully planned, documented process exists. Documentation supporting a plan may exist in one or several documents.

b. The Assessment Team must ensure that the full intent of each section is met. The activity of each area must meet the intent of the Supplier Certification Policy. To that extent, the assessor is not limited to checklist questions; the assessor shall request any information required to fully understand the operational effectiveness of that area.

All questions must be answered; however, checklist questions are intended to function as "signposts" to broader areas that the assessor must address and review.

1.2 DEFINITIONS

Area—An "area" is a combination of "sections". For example, the area of materials acquisition includes the purchasing, receiving, incoming inspection, supplier management, and materials storage sections.

Materials—When the word "materials" is used within this document, it is intended as appropriate to each business. Materials can include raw materials, expendables, subassemblies, assemblies, and packaging materials.

Plan—A program of action defining future-oriented, high level objectives.

Procedure—A procedure is a detailed description of how to conduct business on a daily basis. Procedures shall comply with the objectives established in a plan.

Section—Each checklist represents a "section" of the manufacturing process. For example, purchasing, receiving, and incoming inspection are all separate sections though together they form the "area" of materials acquisition.

1.3 GUIDELINES FOR PERFORMING THE ASSESSMENT

Refer to EL-MF520-01, *Supplier Certification Procedure: Steps to the Supplier Certification Decision* for a detailed description of the assessment procedure.

Guidelines for performing the assessment are listed below.

a. The Assessment Team leader shall have adequate training or experience in the performance of manufacturing assessments.

The team leader shall ensure that each team member has experience commensurate with the requirements of the assessment.

b. The Assessment Team shall begin each audit with a meeting to introduce team members and key plant contacts, and to discuss the assessment procedure and schedule.

c. The assessment shall occur in the following sequence.

Examination of appropriate documentation.
Discussion of the overall system with the responsible contact.
Examination of files, bins, shelves, and stockrooms.

The purpose of the above sequence shall be to determine compliance with the requirements of this document and the intent of the Supplier Certification Policy.

d. The assessor shall at all times be accompanied by the responsible key contact and/or the supervisor of the area being assessed. All observations (both favorable and unfavorable) and recommendations shall be communicated to the key contact before leaving the area.

Assessor observations and recommendaations shall be detailed in writing on the Assessor's Review Form (Exhibit 1) to be be used in conjunction with each checklist.

Less detailed descriptions of the assessor's recommendations shall be included on the Assessment Action Report (Exhibit 2), which is recommended for the development of the supplier's action plan to correct observed discrepancies.

e. Upon completion of the assessment, all results shall be communicated to the supplier's plant and business management in both written and verbal form.

f. The final report shall include a completed checklist corresponding to the Assessor's Review Form and Assessment Action Report. Distribution of the final report shall be limited to those capable of contributing to the corrective action process.

2 CHECKLISTS FOR SUPPLIER CERTIFICATION

2.1 CHECKLIST DISTRIBUTION

The following checklists shall be used by the Assessment Team when performing a supplier evaluation.

Remove the following exhibits and checklists and distribute to team members.

Each team member shall receive a copy of Exhibits 1 and 2.

The checklists shall be distributed to team members according to the Assessment Schedule outlined in EL-MF520-01, *Supplier Certification Policy: Steps to the Supplier Certification Decision.*

2.2 LIST OF EXHIBITS AND CHECKLISTS

Number	Title	Page
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Checklist		
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DIGITAL SUPPLIER CERTIFICATION PROGRAM
EXHIBIT 1: Assessor's Review Form

Assessor's name: Date:

Facility being assessed: Department/Area:

Checklist number(s) from Manufacturing Systems Assessment (EL-MF520-02):

Reference to Supplier Certification Policy (EL-MF520-02) requirements:

Strengths:

Concerns:

Supplier document references:

DIGITAL SUPPLIER CERTIFICATION PROGRAM
EXHIBIT 2: Assessment Action Report

Assessor's name: Date:

Facility being assessed: Department/Area:

Checklist numbers from Manufacturing Systems Assessment (EL-MF520-02):

Reference to Supplier Certification Policy (EL-MF520-02) requirements:

Details:

Suggested action required:

Supplier proposed action:

Agreed to by: Completion date:

Compliance verified by: Date:

Comments:

3 GENERAL SUPPLIER DATA

Supplier _____

Address _____

City _____ State _____ Zip _____

Certification Contact _____

Title _____

Tel. _____

Digital products involved in this assessment:

New Digital products under development at this facility:

4 PRODUCT QUALIFICATION REQUIREMENTS

The following are requirements for the qualification of products manufactured for and supplied to Digital Equipment Corporation.

		Y	N	N/A
a.	Is there a process or method for qualifying products to requirements (tests,reports)?	___	___	___
b.	Is there a specification, under formal revision control, that describes the performance requirements for each product supplied?	___	___	___
c.	Has the supplier prepared and submitted a complete qualification test report that has been reviewed and approved by Digital?	___	___	___
d.	Is there a complete report for compliance of the product(s) to all safety regulations and requirements and approved by Digital?	___	___	___
e.	Has correlation of test results been achieved and agreed upon by Digital and the supplier?	___	___	___
f.	Where systems level tests are required, has a test plan been generated and agreed to by Digital?	___	___	___
g.	Is there a Digital approved Customer Services Plan describing the supplier's method of customer support?	___	___	___
h.	If there is not a Digital approved Customer Services Plan, is a similar plan administered by Digital (considered company confidential)?	___	___	___

5 MANUFACTURING PLANNING

		Y	N	N/A
a.	Is there a product or process manufacturing plan (as appropriate to the business being audited)?	___	___	___
b.	Does the plan include details or strategies relating to:			
	1. Product description?	___	___	___
	2. Build schedules?	___	___	___
	3. Materials and inventory?	___	___	___
	4. Training?	___	___	___
	5. Manufacturing processes and capital equipment?	___	___	___
	6. Subcontracting?	___	___	___
	7. Financial requirements?	___	___	___
	8. Quality and reliability?	___	___	___
	9. Quality information systems?	___	___	___
	10. Quality cost systems?	___	___	___
	11. Certification Programs (product, process, supplier)?	___	___	___
c.	Has the plan been approved by the supplier's management and others responsible for the execution of the plan?	___	___	___
d.	Do strategies have present and future objectives clearly defined?	___	___	___
e.	For each objective, does the plan define:			
	1. Responsibility?	___	___	___
	2. Timing?	___	___	___
	3. Completion criteria?	___	___	___
f.	Is there evidence that the contents of the plan are used to measure progress during the year?	___	___	___
g.	Is it updated when the plans and strategies change?	___	___	___

6 PLANT SYSTEMS AND MANUFACTURING PROCESS ASSESSMENTS

		Y	N	N/A
a.	Is there a procedure(s) to assess, on a continuous basis, the manufacturing and plant support functions, plans, procedures and operations?	___	___	___
b.	Does the procedure define:			
	1. Overall assessment responsibility?	___	___	___
	2. The areas to be assessed?	___	___	___
	3. The frequency of assessment?	___	___	___
	4. Assessment question checklist?	___	___	___
	5. An evaluation of the EFFECTIVENESS of the methods and procedures being assessed, rather than a static assessment of "following the procedure"?	___	___	___
	6. The criteria for and selection of assessors?	___	___	___
	7. Methods for reporting findings and recommendations, including distributions?	___	___	___
	8. Methods for recording corrective action assignments and responsibilities?	___	___	___
	9. Reassessment of deficient areas and verification of closure?	___	___	___
	10. Methods for maintaining records and files?	___	___	___
c.	Is there evidence that the assessment process is performed according to the above procedure?	___	___	___
d.	Are assessments performed by personnel who are not directly responsible for the assessed area?	___	___	___
e.	Does management participate in the assessment activity?	___	___	___

7 MATERIALS OVERVIEW

		Y	N	N/A
a.	Is there a plant/business level plan that addresses the strategy of acquisition and control of materials (including subcontracted materials required by the manufacturing process)?	___	___	___
b.	At a minimum, does the above plan define present and future objectives and strategies for:			
	1. Qualification of suppliers?	___	___	___
	2. Qualification of purchased material and parts?	___	___	___
	3. Supplier Management Program with objectives to reduce inventories, reduce and eliminate inspections, and achieve cost effectiveness?	___	___	___
	4. Material Control?	___	___	___
	5. Inventory Control?	___	___	___
	6. Source Inspection?	___	___	___
	7. Incoming Inspection?	___	___	___
	8. Corrective Action?	___	___	___
c.	Does it define the plant/business functions responsible for accomplishing these objectives and strategies?	___	___	___
d.	Is there a system which measures the effectiveness of the materials acquisition and control functions?	___	___	___
e.	At a minimum, do the measurement results indicate that materials supplied to the manufacturing process are controlled to ensure:			
	1. Quality and reliability?	___	___	___
	2. Correct quantities?	___	___	___
	3. Supplied on time?	___	___	___
f.	Is there evidence that the various departments coordinate their efforts to achieve the objectives of the materials plan?	___	___	___

8 SUPPLIER MANAGEMENT

		Y	N	N/A
a.	Is there a plan and procedure for Supplier Management Programs (for example: Ship-To-Stock, Supplier Certification)?	___	___	___
b.	For each Supplier Management Program employed, are the minimum requirements specified for program completion and ongoing communication, maintenance and support?	___	___	___
c.	Is there evidence that the programs are being managed/implemented according to the plans and supporting documents?	___	___	___
	Are records maintained, on each Supplier Management Program, that contain data to support events completed/to be completed?	___	___	___
d.	Are there systems in place to measure return on investment of the Supplier Management Programs employed (quality, cost, delivery)?	___	___	___
e.	When Supplier Management Programs are used, is there a file on each supplier that contains:			
	1. The milestones required for completion of the program for each supplier?	___	___	___
	2. Comprehensive, up-to-date specifications?	___	___	___
	3. Parts characterization/correlation?	___	___	___
	4. Correlation/inspection reports?	___	___	___
	5. Audit schedule for supplier's manufacturing and support systems?	___	___	___
	6. Audit finding reports?	___	___	___
	7. Supplier responses to audit findings with closure?	___	___	___
f.	When "certification" type programs are used, is there a file on each supplier that contains:			
	1. Required milestones for program completion?	___	___	___
	2. Supplier's own pre-certification audit results and responses?	___	___	___
	3. Results of a review to determine the supplier's readiness for an assessment?	___	___	___
	4. The final assessment report to the supplier and the supplier's responses?	___	___	___
	5. Formal acknowledgment of the certification status?	___	___	___
	6. On-going communication including:			
	a. Supplier's in-process control?	___	___	___
	b. On-going quality/reliability test results?	___	___	___
	c. Final audit test results?	___	___	___
	d. Internal system assessment results?	___	___	___
g.	Are there systems in place that allow the supplier to track the quality level of material received from the supplier under the Supplier Management Program?	___	___	___
	1. Is the data collected from all user sources (such as in-process, customer failures, failure analysis labs, and reliability tests.)?	___	___	___

9 PURCHASING

		Y	N	N/A
a.	Is there a Purchasing plan that supports the supplier's overall Business Plan?	___	___	___
b.	Are there procedures supporting the Purchasing Plan?	___	___	___
c.	Do the plan and procedures contain, at a minimum:			
	1. The supplier evaluation/selection criteria and process (new and existing materials /suppliers)?	___	___	___
	2. The part/product qualification criteria and process?	___	___	___
	3. The technical support required (such as component engineering, manufacturing engineering, quality engineering)?	___	___	___
	a. Listing of current qualified parts /products/suppliers?	___	___	___
	b. Changes (revisions) with amended drawings, specifications, and instructions?	___	___	___
	c. Feedback (such as inspection results, in-process results, non-conforming material reports)?	___	___	___
	d. Product safety reports and evaluations?	___	___	___
	e. Communication timeliness and effectiveness?	___	___	___
	4. The corrective action and improvement process?	___	___	___
	5. Record retention?	___	___	___
	6. Supplier Management Program?	___	___	___
	7. Supplier education (statistical concepts, process capability, process control)?	___	___	___
	8. If subcontracting is used, are subcontracting-unique requirements specified in writing?	___	___	___
d.	Is there evidence that the plan and procedures are constantly evolving and effective?	___	___	___
e.	Is there evidence that the supplier(s):			
	1. Are made aware of how the product will be used?	___	___	___
	2. Advice is solicited, communicated, and implemented as appropriate?	___	___	___
	3. Are visited?	___	___	___
f.	Are reports published regularly highlighting:			
	1. The process for supplier management and corrective actions?	___	___	___
	2. Accomplishments vs. stated objectives?	___	___	___
	3. Future direction?	___	___	___
g.	At a minimum, do the supplier's sub-suppliers receive, via Purchase Orders and supporting documents:			
	1. Correct part number and revision level?	___	___	___
	2. Complete part/product specifications including:			
	a. Part characterization?	___	___	___
	b. Regulatory requirements including UL, CSA, IEC, and VDE?	___	___	___
	c. Requirements (such as flammability testing)?	___	___	___
	d. Shelf life?	___	___	___
	e. Identification of parts?	___	___	___
	f. Container identification (including specification of shelf life, revision level, part level information)?	___	___	___
	g. Labeling?	___	___	___

	h. Packaging, preservation, and shipping requirements?	___	___	___
3.	Test and measurement techniques and equipment?	___	___	___
4.	Quality requirements (including process, product quality, and product reliability)?	___	___	___
5.	Objective product and process feedback data where applicable?	___	___	___

h. Do records show evidence of Engineering evaluation(s) of components?

1.	During initial part(s) qualification?	___	___	___
2.	To support ECO or specification changes to parts or materials?	___	___	___
3.	To resolve suspected parts problems?	___	___	___
4.	To periodically reaffirm parts conformance to specifications?	___	___	___
5.	To specify life, wear, or ongoing reliability testing as requirements for qualification?	___	___	___

10 RECEIVING

		Y	N	N/A
a.	Is there a procedure for the Receiving Department that includes, at a minimum:			
	1. A flow chart of receiving process?	___	___	___
	2. Detailed receiving steps (for example, paperwork, handling, reporting)?	___	___	___
	3. The receiving criteria (such as verification of Purchase Orders and part numbers, revisions, quantities)?	___	___	___
	4. The handling of exceptions (damaged packaging, over shipments)?	___	___	___
b.	For each part/product received, including those on supplier management type programs, are there current delivery locations specified (for example, stockrooms, incoming inspection)?	___	___	___
c.	Is there evidence that the material moves on a "First-In-First-Out" (FIFO) basis through the receiving area?	___	___	___

11 INCOMING INSPECTION

		Y	N	N/A
a.	Is there a procedure for the Incoming Inspection (I.I) Department that includes, at a minimum:			
	1. A flow chart of the I.I. process?	___	___	___
	2. Details of the process steps?	___	___	___
	3. The handling of exceptions (including the material review process, non-conforming material process, waivers, and approval authority)?	___	___	___
	4. The record retention requirements (such as initial qualifications, random inspection audits)?	___	___	___
b.	For each part, is there:			
	1. A documented process and explicit sampling plans?	___	___	___
	2. A documented reference to tools and test equipment, including calibration, maintenance requirements, and schedules?	___	___	___
c.	Are all procedures and other required documentation maintained to ensure revision level controls?	___	___	___
d.	Does a random sample of part numbers confirm that Incoming Inspection is performed according to the I.I. procedures and current revision specifications?	___	___	___
e.	Is there evidence that I.I. equipment is maintained and calibrated according to established schedule?	___	___	___
f.	Is there evidence that material moves on a "first-in-first-out" (FIFO) basis into the I.I. process?	___	___	___
g.	Are there clearly marked process hold areas?	___	___	___
h.	Are accepted and rejected materials clearly identified and separated from each other?	___	___	___
i.	Is there a documented training program for Incoming Inspection personnel that includes, at a minimum:			
	1. Proper use of test and inspection procedures and equipment?	___	___	___
	2. Records of training given?	___	___	___
	3. Measures of effectiveness of the Training Plan?	___	___	___
	4. Proper implementation of statistical sampling plans?	___	___	___
j.	Are periodic reports issued to plant/business staffs highlighting supplier/part performance?	___	___	___
k.	Does I.I. have a system for measuring the effectiveness of its performance?	___	___	___
l.	Are sampling plans/techniques adjusted according to results of in-process data?	___	___	___

12 MATERIALS STORAGE

		Y	N	N/A
a.	Is there a procedure for material storage that includes, at a minimum:			
	1. A flow chart of materials storage and kitting processes?	___	___	___
	2. A controlled record of issue transactions?	___	___	___
	3. Detailed materials kitting procedure?	___	___	___
	4. General storage and handling criteria?	___	___	___
	5. Container and location marking requirements?	___	___	___
	6. The process for dealing with exceptions such as purges, non-conforming material, Engineering Change Orders?	___	___	___
	7. First-in-first-out (FIFO) requirements?	___	___	___
	8. The maintenance/calibration of handling tools and equipment?	___	___	___
b.	For each part/product stored, are there documented requirements for:			
	1. Storage locations?	___	___	___
	2. Any part/product unique handling and storage requirements (such as shelf life, stacking limits, static sensitivity, labeling)?	___	___	___
c.	Is it evident that the procedure(s) and requirements are being adhered to and are effective?	___	___	___
d.	Have capacity specifications been developed for each material storage area (stockroom)?	___	___	___
e.	Are operations within capacity specifications?	___	___	___
f.	Are provisions made for clearly marked process hold areas?	___	___	___
g.	Are provisions made for clearly marked hold areas for exceptions (such as purges)?	___	___	___
h.	Is there a documentation training program for materials storage, handling, or kitting functions that includes:			
	1. Proper use of procedures?	___	___	___
	2. Records of training given?	___	___	___
	3. Measures of effectiveness?	___	___	___

13 MANUFACTURING DOCUMENTATION

		Y	N	N/A
a.	Is there a Manufacturing Process Flow Diagram that reflects the flow of materials and work sequence?	___	___	___
b.	Where applicable, does the diagram indicate:			
	1. Receiving?	___	___	___
	2. Incoming Inspection?	___	___	___
	3. Stockrooms?	___	___	___
	4. Kitting?	___	___	___
	5. Operations?	___	___	___
	6. Process control points?	___	___	___
	7. Inspection?	___	___	___
	8. Test?	___	___	___
	9. Packaging and Shipping?	___	___	___
	10. Audit points?	___	___	___
	11. Electro-static Discharge protection areas?	___	___	___
c.	Are applicable procedures referenced by number at each process step?	___	___	___
d.	In addition to the detailed process items, do the procedures contain instructions for:			
	1. In-process material moving, storage and handling?	___	___	___
	2. Special requirements (handling of static sensitive devices)?	___	___	___
	3. Housekeeping?	___	___	___
e.	Are all items in bins, trays, racks, and skids identifiable as to description, part number, and conformance/non-conformance rework status?	___	___	___
f.	Is there a manufacturing space and department layout (drawing) indicating space and work flow?	___	___	___
g.	Is it evident that this layout represents what actually exists?	___	___	___
h.	Is it evident that:			
	1. The flow is effective?	___	___	___
	2. Adequate space is available?	___	___	___
i.	Are procedures available for all process, inspection, and audit steps?	___	___	___
j.	Is there a documented control system in use for manufacturing support media (such as test tapes) that includes:			
	1. Cleaning and failure verification?	___	___	___
	2. Handling and storage?	___	___	___
	3. Segregation and disposition of failed media?	___	___	___
k.	Is there a documented marking and identification system for in-process materials?	___	___	___
	1. Does the system include requirements for the control of marking devices (such as stamps and bar codes)?	___	___	___
	2. Is there evidence that the system is utilized and effective?	___	___	___
l.	Is there evidence that the procedures reflect the methods, equipment, and materials that are actually being used?	___	___	___

m. Is there evidence that the procedures:

1.	Are being used?	___	___	___
2.	Are clear and easy to read?	___	___	___
3.	Contain effective visual aides?	___	___	___

n.	Is there a documented, closed-loop system that employees can use to input improvements to the processes, procedures, and products?	___	___	___
o.	Is there evidence that procedures exist and are being used to support processes, such as clean room operation?	___	___	___

14 PROCESS DESIGN/CAPABILITY

		Y	N	N/A
a.	Are there design specifications for the process including:			
	1. Output (units per day)?	___	___	___
	2. Time/Unit of output?	___	___	___
	3. Guard-banding requirements for the process?	___	___	___
	4. Quality (yields, Parts Per Million)?	___	___	___
	5. Quality analysis (rework, scrap, touch up)?	___	___	___
	6. Flexibility considerations? (upside, downside)?	___	___	___
b.	For each operation within the process, are there specifications for:			
	1. Time/Unit of output?	___	___	___
	2. Quality?	___	___	___
	3. Quality cost?	___	___	___
	4. Guard-banding requirements?	___	___	___
c.	Is data available indicating that the capability of key operations has been proven and measured?	___	___	___
d.	Is there evidence that when major process changes occur (such as equipment changes and procedure changes) that capability analysis is performed?	___	___	___
e.	Is the entire process measured against the design specification?	___	___	___
f.	Has process capability been proven prior to construction of process control charts?	___	___	___

15 PROCESS CONTROL

		Y	N	N/A
a.	Is there a procedure for process control? Does it specify, at a minimum:	___	___	___
	1. Continuous improvement objectives?	___	___	___
	2. Data collection including methods and locations?	___	___	___
	3. Methods of reporting?	___	___	___
	4. Comparison with the inherent capability of the process?	___	___	___
	5. Frequency and timing of reporting?	___	___	___
	6. Report distribution?	___	___	___
	7. Construction of statistically based control charts?	___	___	___
	8. Training/skill prerequisites?	___	___	___
b.	Is process control data collected at all control points indicated in the process flow diagram?	___	___	___
c.	Is there a designated focus/team responsible for process control data analysis and customer returns analysis?	___	___	___
d.	Is corrective action taken when:			
	1. Process data falls outside established limits?	___	___	___
	2. Trends indicate that additional analysis is required?	___	___	___
e.	Are records of corrective actions referenced above in d completed and maintained by the focus/team?	___	___	___
f.	Does the process control data indicate:			
	1. That the processes are under control?	___	___	___
	2. That the processes are improving?	___	___	___

16 IN-PROCESS NON-CONFORMING MATERIAL CONTROL

		Y	N	N/A
a.	Is there a procedure that specifies the methods and responsibilities for effective control of in-process non-conforming material (NCM)?	___	___	___
b.	Does the procedure provide instructions for:			
	1. Identifying, tagging, confirming and segregating in the work area?	___	___	___
	2. Delivery of confirmed NCM to a secured and segregated storage area?	___	___	___
	3. Authority to review and decide final disposition of NCM?	___	___	___
	4. The disposition process (such as scrap, rework, waiver, return to supplier)?	___	___	___
	5. Ongoing analysis and reporting of the review process, quality trends, supplier problems, and costs?	___	___	___
	6. Inputting chronic or recurring NCM problems to the corrective action system and tracking the result?	___	___	___
c.	When the disposition process results in a waiver, is there evidence that the customer's ability to use the product is evaluated?	___	___	___
d.	Is there evidence that the NCM procedure is:			
	1. Being used effectively?	___	___	___
	2. Timely?	___	___	___

17 DIAGNOSTIC SOFTWARE CONTROL

		Y	N	N/A
a.	Is there a procedure that defines the requirements and responsibilities for the administration, storage, and control of device or system-level diagnostic software used to test product during the build process?	___	___	___
b.	Is there an accurate, up-to-date list of the revision levels of all diagnostic software used in the manufacturing test equipment?	___	___	___
c.	Is there a system for preventing unauthorized changes to all software used to test product?	___	___	___
d.	Is there evidence that the procedure is utilized and is effective, and that the required revised software is being used?	___	___	___

18 CALIBRATION

		Y	N	N/A
a.	Is there a documented system for the calibration of manufacturing equipment?	___	___	___
b.	Does the system include a procedure for the recall of equipment due for calibration with minimum disruption to manufacturing areas?	___	___	___
c.	Does the procedure contain instructions to ensure the integrity of product previously inspected/tested on equipment found to be out of tolerance during calibration?	___	___	___
d.	Is there evidence that management supports the recall system, and that it is operating effectively?	___	___	___
e.	Does the procedure require that all new equipment be calibrated before use?	___	___	___
f.	Are supporting documents supplied by the appropriate authority when manufacturing equipment is determined not to require scheduled calibration?	___	___	___
g.	Are documented, approved procedures used for calibration of equipment?	___	___	___
h.	Are calibration records maintained?	___	___	___
i.	Is calibration data reviewed to ensure the effectiveness of calibration intervals?	___	___	___
j.	Are all reference standards, including those of subcontracted calibration services:			
	1. Traceable to the U.S. National Bureau of Standards?	___	___	___
	2. Calibrated?	___	___	___
	3. Maintained in an appropriate environment?	___	___	___

19 PREVENTIVE MAINTENANCE

		Y	N	N/A
a.	Is there a procedure for preventive maintenance of manufacturing equipment (including, at a minimum, schedules, responsibilities, and record keeping)?	___	___	___
b.	Is there an individual preventive maintenance procedure for each piece of equipment requiring preventive maintenance?	___	___	___
c.	Is there evidence that the preventive maintenance system/procedure is utilized and effective (achieving equipment uptime objectives)?	___	___	___

20 PRODUCT SAFETY

		Y	N	N/A
a.	Does the finished product of the manufacturing system require conformance to the regulations of external agencies (UL, CSA, FCC, VDE)?	___	___	___
	Not: If the answer to "a" is YES, answer the following; if NO, go to the next list.			
b.	Is there a documented system that defines how the requirements of these agencies will be achieved and maintained?	___	___	___
c.	Does the system define and contain, at a minimum:			
	1. A current listing of regulated products?	___	___	___
	2. Test data supporting agency requirements?	___	___	___
	3. Current applicable regulatory standards and specifications?	___	___	___
	4. Assignment of product safety responsibilities (Product Safety Coordinator and alternate)?	___	___	___
	5. Procedures for Product Safety incident investigations?	___	___	___
	6. Employee training and awareness strategies/ implementation?	___	___	___
	7. Requirements for product safety self-audits (including labeling and marking, hypot testing, purchasing systems, and training)?	___	___	___
	8. Product Safety records maintenance?	___	___	___
d.	Is the system's effectiveness evidenced by:			
	1. Self-auditing performed to schedule?	___	___	___
	2. Positive self-audit results?	___	___	___
	3. Positive external agency audit results (such as UL and CSA)?	___	___	___
	4. Effective corrective action?	___	___	___

21 OCCUPATIONAL SAFETY AND HEALTH

		Y	N	N/A
a.	Is there a written Plant Safety policy?	___	___	___
b.	Has responsibility been delegated to staff, department heads, managers, supervisors and employees through policy, operating procedures, and/or job description?	___	___	___
c.	Are responsible persons held accountable?	___	___	___
d.	Is there an established Safety and Health Program in place that addresses:			
	1. Hazardous materials (from purchasing to disposal)?	___	___	___
	2. Occupational hazards?	___	___	___
	3. Disaster control (worker awareness of evacuation plans, diagrams, extinguishers)?	___	___	___
	4. Safety evaluation of new equipment, processes, materials, and plant alterations or additions?	___	___	___
	5. Training?	___	___	___
	6. Self-inspection?	___	___	___
	7. Record keeping?	___	___	___
e.	Is there evidence that the Safety and Health Program is being implemented as designed, and is effective?	___	___	___

22 FACILITIES MANAGMENT

		Y	N	N/A
a.	Is there a facilities management plan?	___	___	___
b.	Does the plan include sections for:			
	1. Heating, ventilation, humidity, air cleanliness, and air conditioning?	___	___	___
	2. Electro-static discharge area maintenance?	___	___	___
	3. Clean room environments and maintenance?	___	___	___
	4. Energy management?	___	___	___
	5. Maintenance training?	___	___	___
	6. Interior and exterior housekeeping?	___	___	___
	7. Electric wiring and apparatus?	___	___	___
	8. Air and water supplies?	___	___	___
	9. Lighting?	___	___	___
	10. Security?	___	___	___
	11. Storage of facilities materials?	___	___	___
	12. Fire protection and prevention material?	___	___	___
c.	For each section, does the plan define:			
	1. Preventive maintenance schedules?	___	___	___
	2. Responsibility?	___	___	___
	3. Timing?	___	___	___
	4. Completion criteria?	___	___	___
d.	Is there evidence that the plan is used and revised as needed?	___	___	___

23 DOCUMENT CONTROL

		Y	N	N/A
a.	Is there a procedure for the control of manufacturing documentation that specifies, at a minimum:			
	1. The central filing system/responsibility?	___	___	___
	2. The documents to be controlled?	___	___	___
	3. Document identification?	___	___	___
	4. Authorized document approval signatures (for originals, temporary/drafts, and revisions)?	___	___	___
	5. The method for document revision?	___	___	___
	6. Maintenance and safeguarding techniques (including control of secure and non-secure documents)?	___	___	___
	7. The methods for document loss and damage protection (such as microfiche cache)?	___	___	___
	8. Distribution of new and revised documents?	___	___	___
	9. Control of revised, temporary, and preliminary documents (approvals, timing, retrieval)?	___	___	___
	10. Techniques for document obsolescence and archiving?	___	___	___
b.	Does a random sample of documents in use match those contained in the master file?	___	___	___
c.	Is there evidence that the document control procedure is being used and is effective?	___	___	___

24 TRAINING

		Y	N	N/A
a.	Is there an overall training Plan, linked with the Business Plan, that identifies:			
	1. Current skill mix?	___	___	___
	2. Future skill needs?	___	___	___
	3. Objectives for training?	___	___	___
	4. Measurement of progress toward objectives?	___	___	___
b.	Are cross-training programs in-place and/or available for support personnel (such as quality, materials, design)?	___	___	___
c.	Does the program curriculum include, at a minimum:			
	1. Process operation, equipment, and tools?	___	___	___
	2. Proper Electro-static discharge equipment and techniques?	___	___	___
	3. Product?	___	___	___
	4. Workmanship, handling, and housekeeping?	___	___	___
	5. Preventive maintenance?	___	___	___
	6. Quality Systems (process capability and control)?	___	___	___
d.	Do program specifics address:			
	1. Program goals?	___	___	___
	2. Process changes?	___	___	___
	3. Ongoing training and retraining?	___	___	___
	4. On the Job Training (OJT)?	___	___	___
	5. Course evaluation and reevaluation?	___	___	___
	6. Trainer evaluation and reevaluation?	___	___	___
	7. Student feedback?	___	___	___
	8. Instructor feedback?	___	___	___
	9. Records?	___	___	___
e.	Is there evidence that the program is being implemented and is effective (meeting program goals, receiving positive student feedback)?	___	___	___
f.	Is there evidence that personnel are properly trained and evaluated prior to working independently?	___	___	___

25 ECO CONTROL

		Y	N	N/A
a.	Is there a procedure in place with a flow diagram describing the administration of change implementation for designs, processes, and specifications?	___	___	___
b.	Does the procedure(s) define:			
	1. The method for notification of:			
	Product and part users?	___	___	___
	Product and part suppliers (materials acquisition)?	___	___	___
	2. The manufacturing process?	___	___	___
	3. Systems to record and report change control break-in by dates or serial numbers?	___	___	___
	4. Method to control out of sequence issues?	___	___	___
	5. Methods for maintenance of documented change status during the implementation cycle?	___	___	___
	6. Is there a procedure that ensures coordinated completion of the change in all areas?	___	___	___
c.	Is there evidence that the system is utilized and effective (changes implemented on schedule, current revision listings on incoming shipments, build revision levels match print revision levels)?	___	___	___

26 RELIABILITY MEASUREMENTS

		Y	N	N/A
a.	Is there a documented program in place that continually measures product reliability?	___	___	___
b.	Has the program been agreed to by the appropriate organizations?	___	___	___
c.	Does the program specify continuously improving reliability goals?	___	___	___
d.	Does the program specify/refer to a specific operating procedure that requires:			
	1. Test equipment?	___	___	___
	2. Testing methods and requirements?	___	___	___
	3. Diagnostics/software?	___	___	___
	4. Accumulation of test hours with time points for read and record?	___	___	___
	5. Methodology of reliability calculations including algorithms used?	___	___	___
	6. Test hours per unit?	___	___	___
	7. Temperature?	___	___	___
	8. Action trends?	___	___	___
	9. Method of selecting and rotating product?	___	___	___
	10. Action points?	___	___	___
	11. Definition of a "failure"?	___	___	___
e.	Is there evidence of a system to:			
	1. Compile and analyze measurement data?	___	___	___
	2. Plot data on statistically based control charts?	___	___	___
	3. Report data to appropriate business group(s)?	___	___	___
	4. Report data in timely manner?	___	___	___
	5. Incorporate action to improve performance?	___	___	___
f.	Is there evidence that the program is operating effectively?	___	___	___

27 PRODUCT AUDIT

		Y	N	N/A
a.	Are there product specific audit procedures with stated objectives for continuous improvement?	___	___	___
b.	Have specific functions been designated to approve the product audit procedures?	___	___	___
c.	Have checklists and defect classifications been documented and agreed to by Digital and the supplier?	___	___	___
d.	Do the results from product audit verify the results as measured in those areas where the products' final evaluations are performed?	___	___	___
e.	Are complete records of audit results maintained?	___	___	___
f.	Is there evidence of a system			
	1. Compile audit data and measure progress toward objectives?	___	___	___
	2. Report data to appropriate business group(s)?	___	___	___
	3. Report data in a timely manner?	___	___	___
	4. Is there evidence that action is taken based on report data?	___	___	___
g.	Is preventive maintenance performed on media and test equipment?	___	___	___
h.	Is there a documented, working system for revision control of product audit:			
	1. Media?	___	___	___
	2. Diagnostics?	___	___	___
	3. Test equipment?	___	___	___

28 RECORD CONTROL

		Y	N	N/A
a.	Is there a procedure for plant/business record control?	___	___	___
b.	Does the procedure define, at a minimum:			
	1. The records to be retained (including revision status, in-process test, and inspection data)?	___	___	___
	2. The length of time the records shall be retained?	___	___	___
	3. Method(s) of storage?	___	___	___
	4. Location of storage?	___	___	___
	5. Indexing techniques (serial number, dates)?	___	___	___
	6. Method for loss and damage protection?	___	___	___
c.	Is there evidence that the record control procedure is being used and is effective?	___	___	___

29 CORRECTIVE ACTION SYSTEM

		Y	N	N/A
a.	Is there a documented corrective action system that addresses problems identified from all data sources, including:			
	1. Quality Information Systems?	___	___	___
	2. Process controls?	___	___	___
	3. Audit results (for process, product, systems)?	___	___	___
	4. Non-conforming material?	___	___	___
	5. Customer?	___	___	___
	6. Internal Control audit results?	___	___	___
b.	Is there a designated cross-functional group that:			
	1. Meets on a regular basis?	___	___	___
	2. Prioritizes problems (with cost/benefit considerations)?	___	___	___
	3. Identifies solutions?	___	___	___
	4. Generates non-conforming material reports?	___	___	___
	5. Specifies responsibilities?	___	___	___
	6. Maintains problem logs?	___	___	___
	7. Monitors corrective action activities?	___	___	___
	8. Incorporates statistical problem solving techniques?	___	___	___
	9. Designs experiments?	___	___	___
	10. Reports problems, commitments, and solutions (including, if necessary, "quality hold/stop shipment" recommendations)?	___	___	___
c.	Are report submitted to higher management when:			
	1. Open/delinquent corrective actions exist?	___	___	___
	2. Problems exist outside the ability of the corrective action team?	___	___	___
d.	Is there evidence that a timely, effective, closed-loop corrective action operation exists?	___	___	___

30 QUALITY INFORMATION SYSTEMS

		Y	N	N/A
a.	Is there a documented Quality Information System in place that, at a minimum, processes data on the:			
	1. Performance of materials?	___	___	___
	2. Performance of processes?	___	___	___
	3. Performance of product?	___	___	___
	4. Customer feedback system?	___	___	___
b.	Does the system provide summary data that allows problems to be quantified for impact on cost and business performance?	___	___	___
c.	Is data reported in a clear, concise, usable manner (examples are pareto analysis and exception reports)?	___	___	___
d.	Is the summary data made available in time to be used for process control maintenance?	___	___	___
e.	Is it distributed and accessible to all functions requiring the information?	___	___	___

31 CONTROL OF PRODUCTION

		Y	N	N/A
a.	Are there processes and procedures in place for the development and control of production schedules (including forecasts, capacity, and materials)?	___	___	___
b.	Does the process include a documented strategy for:			
	1. Continuously reducing in-process inventory (just-in-time concepts)?	___	___	___
	2. Level loading?	___	___	___
c.	Is the effectiveness of the scheduling/control process evidenced by:			
	1. The expected utilization of workers and objectives?	___	___	___
	2. Achievement of in-process inventory objectives (weeks, days, hours)?	___	___	___
	3. On time completion of production schedules?	___	___	___
	4. Absence of end-of-month or end-of-quarter surges?	___	___	___

32 PACKAGING/PACKING/SHIPPING/WAREHOUSING

		Y	N	N/A
a.	Are there documented instructions in use for the packing/packaging of the product (including product variations, if applicable)?	___	___	___
b.	Does the documentation detail, at a minimum:			
	1. What should be packaged (by items, documents, and quantities)?	___	___	___
	2. The packaging process (such as packaging materials, procedures)?	___	___	___
	3. Package/Packing identification (including labels, markings, revision levels)?	___	___	___
c.	Is there evidence, from out-of-box auditing or equivalent measurement techniques, that the packaging/packing operation is effective?	___	___	___
d.	Is there documentation in place that specifies the process and methods of shipping products (schedules, logs, transport-mode selection)?	___	___	___
e.	Is there evidence that selection of the transport mode is based on product requirements (for example, shock and vibration limitations)?	___	___	___
f.	Are there procedures in place that specify special loading and handling requirements?	___	___	___
g.	Is there evidence that transport selection and product handling and loading techniques are well qualified and effective (such as simulated stress testing and customer feedback)?	___	___	___
h.	If warehousing of finished product(s) is utilized:			
	1. Is the product packaging dated conspicuously (for effective stock rotation)?	___	___	___
	2. Does the packaging clearly identify any special handling/stacking/storage information?	___	___	___
i.	Is there evidence that personnel understand the following:			
	1. The use of general operating and product specific documentation?	___	___	___
	2. The use of materials and equipment (including care and maintenance of equipment)?	___	___	___
	3. Safety requirements?	___	___	___
	4. Good housekeeping?	___	___	___
	5. Proper material and product handling?	___	___	___

33 CUSTOMER SATISFACTION

		Y	N	N/A
a.	Is there a plan for the systematic evaluation of customer satisfaction levels?	___	___	___
b.	Is this plan included in the Business Plan?	___	___	___
c.	Does the plan address:			
	1. Product issues?	___	___	___
	2. Communications?	___	___	___
	3. People/support/expertise?	___	___	___
	4. Cost issues?	___	___	___
	5. Policies?	___	___	___
	6. Engineering issues?	___	___	___
d.	Are these elements agreed to by the customer?	___	___	___
e.	Is there an implementation strategy that:			
	1. Defines the customer(s)?	___	___	___
	2. Identifies the required resources?	___	___	___
	3. Provides for the collection of customer feedback?	___	___	___
	4. Specifies the customer satisfaction measurement process and frequency?	___	___	___
f.	Is there a method for reporting the results of collected data that addresses:			
	1. Format, content, and analysis?	___	___	___
	2. Frequency?	___	___	___
	3. Distribution?	___	___	___
g.	Do methods exist for a closed-loop corrective action system that includes:			
	1. Staff review of performance with action items assigned?	___	___	___
	2. Acknowledgment to customers of their inputs and action priorities?	___	___	___
	3. Follow-up to ensure completion of action items?	___	___	___

34 FAILURE ANALYSIS

		Y	N	N/A
a.	Is there a procedure in place which defines the process for receiving, reviewing, and processing returned product?	___	___	___
b.	Does the procedure ensure:			
	1. Segregation until product status is identified?	___	___	___
	2. Finished product integrity (functionality, revision level)?	___	___	___
c.	Is there a documented approach to continuous performance of failure/defect analysis on returned product to determine the root cause of failures?	___	___	___
d.	Is the information gathered from analysis routinely communicated to (the):			
	1. Corrective action system?	___	___	___
	2. Process control?	___	___	___
	3. Customer?	___	___	___
	4. Supplier?	___	___	___
	5. On-going reliability testing?	___	___	___
e.	Is the repair of returned product tracked to measure the effectiveness of failure analysis and the corrective action system?	___	___	___
	1. Is the rate of return of previously repaired units tracked and measured?	___	___	___

35 TRACEABILITY

		Y	N	N/A
a.	Is there a documented business strategy in place that addresses product traceability?	___	___	___
b.	Is there evidence that the development of the strategy took into consideration:			
	1. Legal requirements?	___	___	___
	2. Traceability of product and its origins?	___	___	___
	3. Traceability of critical parts within the product?	___	___	___
c.	Are there procedures in place at required process points that support the traceability strategy?	___	___	___
d.	Is there evidence that the system is being used and is effective?	___	___	___

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